IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MULTIPLE ENERGY TECHNOLOGIES, LLC, Plaintiff, v. UNDER ARMOUR, INC., Defendant.	)	2:20-CV-664-NR

MEMORANDUM OPINION

J. Nicholas Ranjan, United States District Judge

Plaintiff Multiple Energy Technologies, LLC brings four claims against Defendant Under Armour, Inc.: violation of the Lanham Act, violation of the Sherman Act, misappropriation of trade secrets; breach of non-disclosure agreement; tortious interference with contract; tortious interference with prospective business expectancies; unjust enrichment; unfair competition; conversion; a claim for an accounting; and a claim for injunctive relief. Following discovery, Under Armour now moves to exclude the expert report of Alberto Gutierrez. ECF 250. After carefully considering the parties' submissions, the Court will deny Under Armour's motion.

BACKGROUND[1]

MET retained Dr. Gutierrez to "opine about the classification process by the FDA, the intent of the June 8, 2017 letter from the FDA to Hologenix and the statements made by Under Armour about Celliant and the FDA." ECF 251-1, ¶ 4.[2] Dr. Gutierrez worked at the FDA for 25 years in various departments. *Id.* at ¶ 7. At

[1] The Court writes for the parties' benefit, who are familiar with the extensive factual and procedural background, as well as the allegations in the third amended complaint.

[2] Unless otherwise noted, all citations to the record refer to the page number of the ECF filing stamp on the top of each page (rather than the native page number).

the FDA, Dr. Gutierrez "was personally involved with the process by which the FDA responds to requests for information pursuant to section 513(g) and in making determinations of what is a medical device that would be regulated by the FDA." *Id.* at ¶ 8. Dr. Gutierrez is now a consultant who "help[s] device companies navigate the FDA regulatory requirements" and provides "strategic advice on regulatory issues and help[s] companies with submissions to the FDA." *Id.* at ¶ 9.

Along with various FDA regulations and documents, Dr. Gutierrez reviewed twelve documents produced in discovery. *Id.* at p. 39 ("List of Documents Used").

Under Armour filed a motion to exclude Dr. Gutierrez's opinions. After given an opportunity, no party requested an evidentiary hearing and the Court does not believe one is necessary for this motion. *See* Order, ECF 290 (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 155 (3d Cir. 2000)). So the motion is ready for disposition.

LEGAL STANDARD

In considering Under Armour's motion to exclude the expert opinion, the Court applies the following standard. An expert witness's testimony is admissible only if (1) the witness is qualified to testify as an expert, (2) the testimony is reliable, and (3) the testimony is relevant. *See UGI Sunbury LLC v. A Permanent Easement*, 949 F.3d 825, 832 (3d Cir. 2020). If any of these three requirements are not satisfied, the expert's testimony is inadmissible under Rule 702 of the Federal Rules of Evidence. *See id.* The proponent of the expert testimony bears the burden to show by a preponderance of the evidence that their expert's opinion is reliable. *See Oddi*, 234 F.3d at 144.

Under Federal Rule of Evidence 702, the Court serves as the "gatekeeper" of expert testimony by "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). "As gatekeeper, a trial judge has three duties: (1) confirm the witness is a qualified

expert; (2) check the proposed testimony is reliable and relates to matters requiring scientific, technical, or specialized knowledge; and (3) ensure the expert's testimony is sufficiently tied to the facts of the case, so that it fits the dispute and will assist the trier of fact." *UGI Sunbury*, 949 F.3d at 832 (cleaned up).

Expert testimony must be reliable. *Daubert*, 509 U.S. at 589; *see also Kumho Tire Co.*, 526 U.S. at 141. To be sufficiently reliable, the expert's testimony need not have "the best foundation, or even . . . [be] supported by the best methodology or unassailable research." *UGI Sunbury*, 949 F.3d at 834 (citation omitted). Rather, the testimony must be supported by "good grounds," using a reliable methodology. *See id.* A court considers various factors to determine whether the testimony is supported by "good grounds," including: "(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put." *Id.* (citations omitted).

DISCUSSION & ANALYSIS

Under Armour makes four arguments in support of its motion to exclude Dr. Gutierrez's report and testimony, which the Court will address in turn.

I. Qualification.

First, Under Armour argues that "Dr. Gutierrez is not qualified as an expert to opine on advertising or marketing issues, including the intent of the advertisements in question or the impact of those advertisements on consumers" because his background is in chemistry, he has no experience in advertising or consumer perception, and has never studied nor done any consulting work on the impact of advertisements on consumers. ECF 251, p. 8. According to Under Armour,

Dr. Gutierrez's opinion is "purely speculative" with regard to whether Under Armour adopted a "campaign of deception." *Id.* at p. 9. Under Armour also argues that even if Dr. Gutierrez is not being offered as a consumer impact expert, his "campaign of deception" opinion is speculative and unreliable and shouldn't be admitted. ECF 278, pp. 2-4.

To be qualified as an expert, the witness must have "specialized knowledge." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). But the specialized-knowledge requirement is applied "liberally," and the Third Circuit has "eschewed imposing overly rigorous requirements of expertise" so long as the expert has sufficient "generalized qualifications." *Id.* "The basis of [the expert's] specialized knowledge can be practical experience as well as academic training and credentials." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (citation omitted) (internal quotation marks omitted). Further, the expert does not need "to be the best qualified or . . . have the specialization that the court considers most appropriate." *Pineda v. Ford Motor Co.,* 520 F.3d 237, 244 (3d Cir. 2008) (citation omitted). Instead, the proffered expert witness need only possess some "skill or knowledge greater than the average layman" that is relevant to the issue at hand. *Elcock*, 233 F.3d at 741 (cleaned up).

The Court concludes that Dr. Gutierrez is qualified to offer an opinion on Under Armour's statements about Celliant and the FDA. Dr. Gutierrez is not being offered as an expert on the intent or consumer impact of advertisements— instead, Dr. Gutierrez is being offered "to opine about the classification process by the FDA, the intent of the June 8, 2017 letter from the FDA to Hologenix and the statements made by Under Armour about Celliant and the FDA." ECF 251-1, ¶ 4; ECF 276, p. 6. Dr. Gutierrez worked at the FDA for 25 years in various positions, ultimately holding a director position. ECF 251-1, ¶ 7. In that time, Dr. Gutierrez was "personally involved with the process by which the FDA responds to requests for

information pursuant to section 513(g) and in making determinations of what is a medical device that would be regulated by the FDA." ECF 251-1, ¶ 8. After his career in the FDA, Dr. Gutierrez joined a consulting group that helps companies navigate FDA regulatory requirements. *Id.* at ¶ 9.

In determining whether an expert is qualified under Rule 702, the focus is on "whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.,* No. 13-2445, 2020 WL 6887885, at *2 (E.D. Pa. Nov. 24, 2020). Dr. Gutierrez's extensive experience at the FDA and with the consulting firm meets this liberal qualification standard and the Court finds that Dr. Gutierrez has the specialized knowledge necessary to testify about Under Armour's statements about Celliant that reference the FDA. *Id.*

II. Independent analysis.

Second, Under Armour argues that even if Dr. Gutierrez is not qualified as an expert in the field of consumer perception, his report should be excluded because he did not perform any independent analysis. ECF 251, p. 10. Under Armour argues that Dr. Gutierrez "took counsel's word for it" that Under Armour engaged in a campaign of deception and did not review data related to consumers visiting websites containing the advertisements at issue, how long each website was active, or how many products with Celliant Under Armour sold in a given year. *Id.* at pp. 10-11. Under Armour further argues that the "campaign of deception" opinion is not based on independent analysis. ECF 278, pp. 4-5.

The Court finds that Dr. Guttierez did perform sufficient independent analysis. Under Armour objects to Dr. Gutuerrez's statement that Under Armour engaged in a "campaign of deception." Dr. Gutierrez concluded in his report that Under Armour's statements about Celliant were false in light of FDA regulations and practices. ECF 251-1, ¶¶ 45-46. He further opined that the statements in the documents that he

reviewed were "false, deceptive and misleading" because the FDA had not determined that Celliant products led to faster recovery, only that the health-related claims made by Hologenix would qualify Celliant products as medical devices. *Id.* Under Armour, by claiming that Dr. Gutierrez is not qualified as an expert on the intent of advertisements, attacks Dr. Gutierrez's conclusions by stating that he "took counsel's word for it" about Under Armour's intent to deceive. But that isn't quite right. Dr. Gutierrez did not purport to opine on Under Armour's intent in the advertisements—instead, he concluded based on his knowledge and expertise that the statements were false, not that Under Armour intended to deceive consumers. Dr. Gutierrez's opinions are based on his independent analysis of FDA regulations and statements advertising products made with Celliant.

III. Documents and conclusions.

Third, Under Armour argues that the documents Dr. Gutierrez relied on do not support his conclusions. ECF 251, pp. 12-13. Additionally, Under Armour objects to the use of the phrase "FDA approval" in Dr. Gutierrez's report (ECF 251-1, ¶ 45) and argues that his report should be excluded because he reviewed no documents with that specific claim. ECF 278, pp. 5-6.

The Court finds the documents Dr. Gutierrez reviewed support his opinions, and any argument that they do not goes to the weight, and not the admissibility, of his opinion. Concerns about the documents an expert reviewed go to the weight of the evidence, not the admissibility, and are appropriately addressed in cross-examination. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006). An expert has "good grounds" for relying on documents containing statements regarding the FDA because they are the type of documents an expert reviewing whether statements are consistent with FDA regulations would rely upon. *See TAKTL, LLC v. IWR, N. Am., LLC*, No. 18-1546, 2024 WL 4343141, at *10 (W.D. Pa. Sept. 30, 2024) (Cercone, J.). Dr. Gutierrez's report states that he reviewed Under

Armour product pages from its website and from Amazon, and he also reviewed a letter from the FDA to Holegenix. *See* ECF 251-1, ¶¶ 39-49. Additionally, Dr. Gutierrez reviewed an article stating that Celliant fabric had received "FDA approval" as a medical device. *Id.* at ¶ 50. Therefore, Under Armour's "challenges to the sufficiency of the factual foundation underlying [Dr. Gutierrez's] opinions go to the weight of his testimony, not its admissibility." *TAKTL, LLC*, 2024 WL 4343141 at *10.

IV. Opinions about FDA regulations.

Fourth, Under Armour argues that Dr. Gutierrez's report contains impermissible legal opinions on the applicability of FDA regulations to the case. ECF 251, pp. 13-14; ECF 278, pp. 7-8.

The Court finds that Dr. Gutierrez's opinions about the FDA's regulations and procedures are relevant and are not legal opinions. "[C]ourts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper." *In re Wellbutrin SR Antitrust Litig.*, No. 04-5525, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010) (collecting cases). Often, such expert testimony is appropriate background testimony that can be helpful to the jury. *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006). Courts frequently admit the type of expert testimony that Dr. Gutierrez offers, and the Court sees no issues with admitting his opinions here. *See*, *e.g.*, *In re: Flonase Antitrust Litig.*, 907 F. Supp. 2d 637, 646 (E.D. Pa. 2012); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (denying motion to exclude expert and allowing her to testify about a "complex regulatory framework" because "her understanding of FDA regulations" would be helpful to a jury); *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 467 (S.D.N.Y. 2016) (allowing expert to testify about compliance with FDA regulations). Dr. Gutierrez may testify so long as he does not give an opinion as to what is required

under the law. *United States ex rel. Penelow v. Janssen Prods., LP*, No. 12-7758, 2022 WL 94535, at *5 (D.N.J. Jan. 10, 2022) (allowing expert to testify about background information but not legal conclusions).

CONCLUSION

For the reasons discussed above, the Court will deny Under Armour's motion to exclude Dr. Gutierrez's expert report. ECF 250. A separate order follows.

DATED: January 13, 2025

BY THE COURT:

/s/ *J. Nicholas Ranjan*
United States District Judge